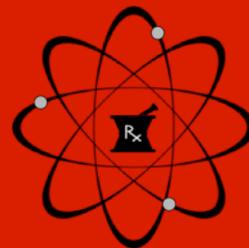


The Nuclear Monthly Missive



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RADIOACTIVIST
AREA**



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APhA-APPM Nuclear Pharmacy Practice SIG New Practitioners Committee

May 2013

Child of the '60s

Dennis Swanson. If you ask him about his job, about what he does daily, he will quickly tell you that he is “35% retired.” But if you listen to the rest of his story, you’ll realize that the 35% is actually much lower. Dennis started his pharmacy career in community pharmacy, shortly after graduating



from the University of Iowa in 1971. He switched from community to the University’s Student Health Center Pharmacy, but after several years, he realized that this world of traditional pharmacy was not for him. He needed a change. He needed a challenge. Mr. Swanson had heard about the nuclear pharmacy program at University of Southern California from a friend and thought that it could be just the jolt his career needed. After receiving a grant that covered his tuition and some expenses, he moved to California with his wife and children to start the Master of Science in Nuclear Pharmacy program under Walter Wolf. He tells me it was a “minimum risk chance to try something different.”

Upon completion of the Master’s degree, Mr. Swanson moved to Michigan, where he oversaw the nuclear pharmacy at the University of

Did you know...

Did you know that the idea of a commercial centralized nuclear pharmacy was introduced in 1972?

Michigan. In this position, he became extensively involved in radiopharmaceutical research and development. Writing IND and IRB applications, Dennis was responsible for ensuring that all of the necessary paperwork was completed so that clinical trials could commence. The research group at this University was large, and Dennis played a vital role in their success. Ever heard of I-131 iodocholesterol? They developed that. How about I-131 MIBG? Yeah, they developed that one, too. Because both of these agents were considered orphan drugs and were going to be distributed to other institutions, the nuclear pharmacy was required to register with the FDA as a drug manufacturer, which ultimately introduced Dennis to a new set of regulations. Hello, cGMP!

“As your body of knowledge increases, your career evolves in different directions.”

In 1983, Mr. Swanson left his role at the University of Michigan and started as the Director of Radiology Pharmacy Services at Henry Ford Hospital in Detroit. Although this position allowed him to continue his involvement in nuclear pharmacy, he was able to expand his practice to include all the drugs used in medical imaging and radiology. You can learn more about



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Suggestions for next month’s newsletter? Contact Ashley Mishoe at AshleyMishoe@me.com.

these in his book, *Pharmaceuticals in Medical Imaging*, which he wrote during his 5-year stint in Detroit.

Dennis headed back east in 1988, where he was hired as the Assistant Dean for Special Projects at the University of Pittsburgh College of Pharmacy. Because the program was developing a Drug Information center, Mr. Swanson was involved in the startup processes of the center, as well as the beginnings of the Investigational Drug Service. He also was able to continue in radiology as one of the principal investigators at the University's PET facility and at their MRI research facility. After an FDA audit graciously left the PET facility with a gift of several pages of violations, Dennis was asked by the University's legal counsel to head the Radioactive Drug Research Committee, and shortly thereafter, the Institutional Review Board. It was here that his involvement with regulatory affairs started the uphill climb. He tells me, "When in research and development, you are subjected to regulations from many entities." And although he never intended to go into regulatory compliance, this pathway evolved from the positions he held before. Dennis adds, "As your body of knowledge increases, your career evolves in different directions." With the different roles he fulfilled throughout his career, I was compelled to ask what he liked most about his job. "Not much," he tells me. "Wow. Tell me how you really feel," I prod. Dennis chuckles and insists that he is (mostly) kidding. He loves being able to assist investigators in the research process, especially because the steps needed to start clinical trials can be quite complex. Unfortunately, this also leads to "police work" and enforcing compliance, which is where the stress comes. When he tells me that he is "a child of the '60s," it is understood that policing is not his forte. He continues to tell me that he originally saw himself pursuing a career in academia, but quickly adds, "I would do it all the same way again if I had to repeat it."

Yes, Mr. Swanson is committed to quality through his efforts at the University of Pittsburgh, but he also stays active in the advancement of nuclear pharmacy on a national level. He collaborates with the FDA through his involvement with SNMMI's FDA Task Force committee and through the Committee on Pharmacopeia. Additionally, Dennis has served on the NRC's Advisory Committee for Medical Use of Isotopes for six years, during which time he assisted in the revision of 10 CFR Part 35. He explains that he likes to push the envelope at the federal level -- and his recent FDA White Paper submission shows just that. In this paper, Mr. Swanson urges the FDA to revisit the approval process of radioactive drugs, specifically the new PET imaging biomarkers, pointing out that the use of a radioactive drug for measuring a biomarker does not technically meet the FDA's definition of a "drug," and therefore, new criteria is necessary for obtaining approval for and regulating these agents.

Dennis has served as the past chair of the Nuclear SIG, as well as several committee chairs throughout his membership with APhA. And speaking of APhA, he has been designated as an APhA Fellow and was a former recipient of the Briner award. When reflecting on his thoughts of winning this distinguished award, he told me that Captain Briner was a close friend of his and actually was a key influence in his start in regulatory affairs. He adds, "When honored like that, it doesn't get much better."

"I would do it all the same way again if I had to repeat it."

Although he is mostly retired now, Mr. Swanson's most recent position was the founding Director of the Office for IND and IDE (Investigational Device Exemption) Support at the University of Pittsburgh. This office, which opened in 2006, processes the University's IND and IDE applications (over 150 since opening), and serves as a support to clinical investigators throughout

the University. In addition to directing this office, Dennis also serves as the chair of the Radiation Safety Committee and the Radioactive Drug Research Committee. Although he has not been involved in research for several years, he plans to focus more on this in his retirement. Because he foresees the future of nuclear pharmacy heading in the PET direction, Dennis would like to become more involved with PET research. He tells me that “PET is fascinating -- and from a research standpoint, it is probably as wide-open as your imagination right now.” He also anticipates more PET companion diagnostics coming available, as well as more biomarker applications.

But aside from dabbling in PET research in his newly-gained free time, he plans to spend more time with his family, including three children and a grandchild. Maybe he’ll watch some more hockey (a sports love he found during his stay in Michigan), or maybe he’ll do more dancing. Dennis tells me he’s “really into disco” . . . I told you he’s a child of the 60’s, right? Maybe it’s just me, but I think a dance-off is needed between Mr. Swanson and CAPT Fejka. * Disco versus international folk dance? I would actually pay to see that.

Want to be a part of this nuclear pharmacy future Dennis speaks so positively of? Mr. Swanson’s advice is to know your regulations, and get involved from a regulatory standpoint. Dennis tells me that following the guidelines and regulations, and knowing the ins and outs of these, blossomed his career. Because he was committed to quality, physicians would seek his input and would collaborate with him when starting new research to ensure their clinical trials would receive the IRB’s and FDA’s stamps of approval. As the field of nuclear pharmacy expands, he

urges you to continue to learn all you can about our niche of pharmacy. Mr. Swanson tells me that he was fortunate to receive a grant to learn something new when he moved to California, and every step in his career after that was ultimately based on an offer to learn even more -- from radiology, to research and regulatory affairs. He ends our discussion by encouraging new practitioners and students to seek opportunities to acquire new skill-sets, offering that “If anyone offers you money to learn something new, take it. Because nobody can ever take away your knowledge.”

Until next time,

Ashley Mishoe

*CAPT Fejka was a part of the Duquesne Tamburitzans and was featured in January’s *Monthly Missive*.

